MRID No. 438140-03

DATA EVALUATION RECORD
§ 71-4 -- AVIAN REPRODUCTION TEST

1. **CHEMICAL:** Dicamba. PC Code No.: 029806

2. **TEST MATERIAL:** Technical Dicamba. Purity: 86.9%

3. **CITATION:**

Authors:	J.B. Beavers, D. Haberlein, L.R. Mitchell, and M. Jaber
Title:	Technical Dicamba: A Reproduction Study with the Mallard
Study Completion Date:	October 7, 1994
Laboratory:	Wildlife International Ltd., Easton, MD.
Sponsor:	Sandoz Agro, Inc., Des Plaines, IL
Laboratory Report ID:	131-183
MRID No.:	438140-03
DP Barcode:	D220472

4. **REVIEWED BY:** Rosemary Graham Mora, M.S., Associate Scientist
KBN Engineering and Applied Sciences, Inc.

Signature: for RGM **Date:** 3/4/96

APPROVED BY: Pim Kosalwat, Ph.D., Senior Scientist
KBN Engineering and Applied Sciences, Inc.

Signature: P. Kosalwat **Date:** 3/4/96

5. **APPROVED BY:**

Signature: **Date:** 5-30-96

6. **STUDY PARAMETERS:**

Scientific Name of Test Organism: *Anas platyrhynchos*
Age of Test Organisms at Test Initiation: 19 weeks
Definitive Study Duration: 21 weeks

7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements for an avian reproduction study using mallard ducks. The NOEC for mallard ducks exposed to technical Dicamba was 800 ppm based upon an apparent reduction in hatchability at 1600 ppm.

Results Synopsis

Most sensitive endpoints: Number of hatchlings and 14-day survivors, and hatchlings and 14-day survivors as percentages of eggs laid and eggs set.

NOEC: 800 ppm (695 ppm ai) LOEC: 1600 ppm (1390 ppm ai)

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VALIDATION SHEET CRF #_____ PAGE ____ OF ____

FORMULATION:		
% a.i.	SC #	CHEMICAL NAME
26.5%		Banvel 2S
		029806

IA	IB	T	FW	EC	R		

Validator: Charles A. Bowen II (1st) Date: 8/11/78

Test Type: Acute oral LD50 in Mallard duck

Test ID.# 233292

CITATION: Fink, Robert. 1977. Acute Oral LD50 - Mallard Duck Banvel 2S Final Report. Conducted by Wildlife International LTD. Sponsored by Velsicol Chemical Corporation.

VALIDATION CATEGORY: Invalid for formulated product

RESULTS: The eight day acute oral LD50 is estimated to be greater than 4640.0 mg/kg. This value was generated by administering dosages of toxic material that were assumed to contain 100.0% active ingredient. Banvel 2S contains only 26.5% active ingredient. The above LD50 value when adjusted for the technical grade amounts to an estimated Acute oral LD50 of greater than 1229.6 mg/kg. See attached abstract for details of experimental esign and procedures.

VALIDATION CATEGORY RATIONALE:

The above study was deemed Invalid because the registrant failed to indicate whether or not experimental birds were properly fasted prior intubation of the experimental material. No statistical analysis was conducted as only one experimental mortality occurred during the course of this bioassay.

CATEGORY REPAIRABILITY:

This bioassay will be re-examined provided the testing facility indicates whether or not both experimental and control birds were properly fasted prior to intubation of toxic material and the control vehicle.

VALIDATION SHEET CRF #_____ PAGE ____ OF ____

FORMULATION:			IA	IB	T	FW	EC	R		
% a.i.	SC #	CHEMICAL NAME	Validator: Charles A Bowen II					Date: 8/11/77		
26.5%		Banvel 2S	Test Type: 48-hour static invertebrate (Daphnia) bioassay							
		Sodium salt ?	Test ID.# 233292							
		029706								

CITATION: Vilkas, Algirdas. 1977. The Acute Toxicity of Banvel 2S to the Water Flea Daphnia magna Straus. Conducted by Union Carbide Environmental Services. Sponsored by Velsicol Chemical Company.

VALIDATION CATEGORY: Core for formulated product.

RESULTS: 48-hour LC50 = 38.1 mg/l
95% confidence limits = (32.7 to 44.3) mg/l
The no effect level was estimated to be less than 18.0 mg/l.

Banvel 2S contains only 26.5% active ingredient. The above values when corrected for the technical would be as follows:

48-hour LC50 = 10.09 mg/l (8.66 to 11.73) mg/l
No effect level was estimated to be less than 4.77 mg/l.

Physical/Chemical parameters existing during bioassay.

Water quality = soft
Temperature = 19.0°C + 1°C
pH = 7.4-7.52
Hardness = 52.0 mg/l as $CaCO_3$
Total alkalinity = 27.0 mg/l
Specific conductivity = 125 umhos/cm

VALIDATION CATEGORY RATIONALE:

The above study was found to concur with EPA present guidelines concerning freshwater static bioassays on Daphnia magna. A Finney Probit analysis was conducted on the testing facility's raw data; results of this statistical check are shown on the following page.

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EEE BRANCH REVIEW

DATE: IN _____ OUT 8/15/78 IN _____ OUT _____ IN _____ OUT _____

FISH & WILDLIFE ENVIRONMENTAL CHEMISTRY EFFICACY

FILE OR REG. NO. 876-ERG

PETITION OR EXP. PERMIT NO. _____

DATE DIV. RECEIVED _____

DATE OF SUBMISSION _____

DATE SUBMISSION ACCEPTED _____

TYPE PRODUCTS(S): I, D, (H) F, N, R, S _____

DATA ACCESSION NO(S). 233292

PRODUCT MGR. NO. Taylor

PRODUCT NAME(S) Banvel 2S

COMPANY NAME Velsicol Chemical Corporation

SUBMISSION PURPOSE Data Review

CHEMICAL & FORMULATION Sodium salt of dicamba = 23.32%

Sodium salts of related acids = 3.18%

Inert ingredients = 73.50%

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(3)

EEE BRANCH REVIEW

DATE: IN 2/25/77 OUT 2/25/77 IN _____ OUT _____ IN _____ OUT _____

FISH & WILDLIFE ENVIRONMENTAL CHEMISTRY EFFICACY

FILE OR REG. NO. 876-255

PETITION OR EXP. PERMIT NO. _____

DATE DIV. RECEIVED _____

DATE OF SUBMISSION _____

DATE SUBMISSION ACCEPTED _____

TYPE PRODUCT(S): I, D, H, F, N, R, S _____

PRODUCT MGR. NO. Taylor (25)

PRODUCT NAME(S) Banvel 2S

COMPANY NAME Velsicol Chem. Corp.

SUBMISSION PURPOSE New Application (Registration)

CHEMICAL & FORMULATION Sodium Salt of dicamba

3, 6-dichlord-o-anisic acid 23.32%
Sodium salts of related acids 3.18%

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DATA EVALUATION RECORD

1. CHEMICAL: Dicamba, Aluminum salt

2. FORMULATION: VEL 4359 50% WP - contains 55% dicamba aluminum salt (ie., 50% dicamba) plus 11% related aluminum salts

3. CITATION: Beavers, J. (1981) Eight-Day Dietary LC50 - Bobwhite Quail CN-10-4359T 50WP - Final Report; received 2/11/82 under 876-443; unpublished report prepared by Wildlife International Ltd for Velsicol Chemical Corp, Chicago, Ill (in Acc #246814)

4. REVIEWED BY: Stephen M. Hopkins /s/
Plant Physiologist
EEB/HED

5. DATE REVIEWED: 4/5/82

6. TEST TYPE: Avian Dietary LC_{50} - Bobwhite Quail

7. REPORTED RESULTS:

The author reported that the dietary LC_{50} of the test material to the bobwhite quail is greater than 5620 ppm aluminum dicamba (approximately 10,000 ppm of the 50 WP).

8. REVIEWER'S CONCLUSIONS:

This study is scientifically sound, but is classified as supplemental due to failure to test the technical grade of the active ingredient, and lack of requirement for an avian dietary LC_{50} study on the formulated product at this time.

Tou Dic 06
029806

DATA EVALUATION RECORD

1. CHEMICAL: Dicamba, Aluminum salt

2. FORMULATION: VEL 4359 50% WP - contains 55% dicamba aluminum salt (ie., 50% dicamba) plus 11% related aluminum salts

3. CITATION: Forbis, A. (1981) Acute Toxicity of CN-10-4359T to Daphnia magna; received 2/11/82 under 876-443; unpublished report prepared by Analytical Bio-Chemistry Laboratories, Inc for Velsicol Chemical Corp., Chicago, Ill (in Acc #246814)

4. REVIEWED BY: Stephen M. Hopkins
Plant Physiologist
EEB/HED

5. DATE REVIEWED: 4/6/82

6. TEST TYPE: Aquatic Invertebrate Acute LC_{50} - Daphnia magna

7. REPORTED RESULTS:

The author reported that the 48 hr LC_{50} of VEL 4359 50W to Daphnia magna is 170 ppm, with a 95% confidence interval of 100-320 ppm. The LC_{50} is equivalent to 93 ppm ai aluminum dicamba.

8. REVIEWER'S CONCLUSIONS:

This study is scientifically sound, but is classified as supplemental due to failure to test the technical grade of the active ingredient, and lack of requirement for an aquatic invertebrate acute LC_{50} study on the formulated product at this time.

Tox Dic 04
029806

DATA EVALUATION RECORD

1. CHEMICAL: Dicamba, Aluminum salt

2. FORMULATION: VEL 4359 50% WP - contains 55% dicamba aluminum salt (ie., 50% dicamba) plus 11% related aluminum salts

3. CITATION: Griffer, J. (1981) Acute Toxicity of CN-10-4359T to Rainbow Trout; received 2/11/82 under 876-443; unpublished report prepared by Analytical Bio-Chemistry Laboratories, Inc for Velsicol Chemical Corp., Chicago, Ill (in Acc #246814)

4. REVIEWED BY: Stephen M. Hopkins
Plant Physiologist
EEB/HED
/s/

5. DATE REVIEWED: 4/6/82

6. TEST TYPE: Fish Acute LC_{50} - Rainbow Trout

7. REPORTED RESULTS:

The author reported that the 96 hr LC_{50} of VEL 4359 50W to the rainbow trout is 88 ppm, which is equivalent to 48 ppm aluminum dicamba. EEB calculate a 95% confidence interval of 56 ppm to infinity.

8. REVIEWER'S CONCLUSIONS:

This study is scientifically sound, but is classified as supplemental due to failure to test the technical grade of the active ingredient, and lack of requirement for a fish acute LC_{50} study on the formulated product at this time.

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DATA EVALUATION RECORD

1. CHEMICAL: Dicamba, Aluminum salt

2. FORMULATION: VEL 4359 50% WP - contains 55% dicamba aluminum salt (ie., 50% dicamba) plus 11% related aluminum salts

3. CITATION: Griffen, J. (1981) Acute Toxicity of CN-10-4359T to Bluegill Sunfish received 2/11/82 under 876-443; unpublished report prepared by Analytical Bio-Chemistry Laboratories, Inc for Velsicol Chemical Corp., Chicago, Ill (in Acc #246814)

4. REVIEWED BY: Stephen M. Hopkins /S/
Plant Physiologist
EEB/HED

5. DATE REVIEWED: 4/6/82

6. TEST TYPE: Fish Acute LC_{50} - Bluegill sunfish

7. REPORTED RESULTS:

The author reported that the 96 hr LC_{50} of VEL 4359 50W to the bluegill sunfish is 130 ppm with a 95% confidence interval of 100-180 ppm. The LC_{50} is equivalent to 71 ppm ai aluminum dicamba.

8. REVIEWER'S CONCLUSIONS:

This study is scientifically sound, but is classified as supplemental due to failure to test the technical grade of the active ingredient, and lack of requirement for a fish acute LC_{50} study on the formulated product at this time.

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DATA EVALUATION RECORD

1. CHEMICAL: Dicamba, Aluminum salt

2. FORMULATION: VEL 4359 50% WP - contains 55% dicamba aluminum salt (ie., 50% dicamba) plus 11% related aluminum salts

3. CITATION: Beavers, J. (1981) Acute Oral LD_{50} - Mallard Duck CN-10-4359T 50WP - Final Report; received 2/11/82 under 876-443; unpublished report prepared by Wildlife International Ltd for Velsicol Chemical Corp, Chicago, Ill (in Acc #246814)

4. REVIEWED BY: Stephen M. Hopkins
Plant Physiologist
EEB/HED

5. DATE REVIEWED: 3/1/82

6. TEST TYPE: Avian acute oral LD_{50} - Mallard Duck

7. REPORTED RESULTS:

The author reported that the acute oral LD_{50} of the test material to the mallard duck is greater than 2510 mg aluminum dicamba per kg of bird weight (approximately 4560 mg of the 50 WP per kg).

8. REVIEWER'S CONCLUSIONS:

This study is scientifically sound, but is classified as supplemental due to failure to test the technical grade of the active ingredient, and lack of requirement for an avian acute oral LD_{50} study on the formulated product at this time.

Tox Dic 02
029806

DATA EVALUATION RECORD

1. CHEMICAL: Dicamba, Aluminum salt

2. FORMULATION: VEL 4359 50% WP - contains 55% dicamba aluminum salt (ie., 50% dicamba) plus 11% related aluminum salts

3. CITATION: Beavers, J. (1981) Eight-Day Dietary LC50 - Mallard Duck CN-10-4359T 50WP - Final Report; received 2/11/82 under 876-443; unpublished report prepared by Wildlife International Ltd for Velsicol Chemical Corp, Chicago, Ill (in Acc #246814)

4. REVIEWED BY: Stephen M. Hopkins /S/
Plant Physiologist
EEB/HED

5. DATE REVIEWED: 3/18/82

6. TEST TYPE: Avian acute oral LC_{50} - Mallard Duck

7. REPORTED RESULTS:

The author reported that the dietary LC_{50} of the test material to the mallard duck is greater than 5620 ppm aluminum dicamba (approximately 10,000 ppm of the 50 WP).

8. REVIEWER'S CONCLUSIONS:

This study is scientifically sound, but is classified as supplemental due to failure to test the technical grade of the active ingredient, and lack of requirement for an avian dietary LC_{50} study on the formulated product at this time.

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DATA EVALUATION RECORD

1. CHEMICAL: Dicamba, Aluminum salt

2. FORMULATION: VEL 4359 50% WP - contains 55% dicamba aluminum salt (ie., 50% dicamba) plus 11% related aluminum salts

3. CITATION: Beavers, J. (1981) Acute Oral LD_{50} - Mallard Duck CN-10-4359T 50WP - Final Report; received 2/11/82 under 876-443; unpublished report prepared by Wildlife International Ltd for Velsicol Chemical Corp, Chicago, Ill (in Acc #246814)

4. REVIEWED BY: Stephen M. Hopkins /s/
Plant Physiologist
EEB/HED

5. DATE REVIEWED: 3/1/82

6. TEST TYPE: Avian acute oral LD_{50} - Mallard Duck

7. REPORTED RESULTS:

The author reported that the acute oral LD_{50} of the test material to the mallard duck is greater than 2510 mg aluminum dicamba per kg of bird weight (approximately 4560 mg of the 50 WP per kg).

8. REVIEWER'S CONCLUSIONS:

This study is scientifically sound, but is classified as supplemental due to failure to test the technical grade of the active ingredient, and lack of requirement for an avian acute oral LD_{50} study on the formulated product at this time.

CASE GS0065 DICAMBA PM 500 06/09/82

CHEM 029806 Sodium dicamba (3,6-dichloro-2-anisic

BRANCH EEB DISC 40 TOPIC 05100542

FORMULATION 90 = FORMULATION NOT IDENTIFIED

FICHE/MASTER ID 00025328 CONTENT CAT 01

Fink, R. (1975) Final Report: Eight-Day Dietary LC-50--Bobwhite Quail: Project No. 107-105. (Unpublished study including official analytical report, received Jan 20, 1975 under 876-EX-29; prepared by Truslow Farms, Inc., submitted by Velsicol Chemical Corp., Chicago, Ill.; CDL:210050-J)

SUBST. CLASS = S.

DIRECT RVW TIME = (MH) START-DATE END DATE

REVIEWED BY: L.W. Touart
TITLE: Fisheries Biologist
ORG: EEB/HED
LOC/TEL:

SIGNATURE: L.W.Touart DATE: 1/10/83

APPROVED BY:
TITLE:
ORG:
LOC/TEL:

SIGNATURE: DATE:

2022200

CASE GS0065 DICAMBA PM 500 06/09/82

CHEM 029806 Sodium dicamba (3,6-dichloro-2-anisic

BRANCH EEB DISC 40 TOPIC 05103043

FORMULATION 90 = FORMULATION NOT IDENTIFIED

FICHE/MASTER ID 00022539 CONTENT CAT 01

Bentley, R.E. (1974) Acute Toxicity of Banvel 2S to Bluegill ("Lepomis macrochirus"). (Unpublished study received Jan 20, 1975 under 876-EX-29; prepared by Bionomics, EG&G Environmental Consultants, submitted by Velsicol Chemical Corp., Chicago, Ill.; CDL:210050-A)

SUBST. CLASS = S.

DIRECT RVW TIME = (MH) START-DATE END DATE

REVIEWED BY: L.W. Tourart
TITLE: Fisheries Biologist
ORG: EEB/HED
LOC/TEL:

SIGNATURE: L.W. Tourart DATE: 1/4/83

APPROVED BY:
TITLE:
ORG:
LOC/TEL:

SIGNATURE: DATE:

2022201

CASE GS0065 DICAMBA PM 500 06/09/82

CHEM 029806 Sodium dicamba (3,6-dichloro-2-anisic

BRANCH EEB DISC 40 TOPIC 05103043

FORMULATION 90 = FORMULATION NOT IDENTIFIED

FICHE/MASTER ID 00029623 CONTENT CAT 01

Bentley, R.E. (1974) Acute Toxicity of Banvel 2S to Rainbow Trout ("Salmo gairdneri"). (Unpublished study received Jan 20, 1975 under 876-EX-29; prepared by Bionomics, EG&G, Environmental Consultants, submitted by Velsicol Chemical Corp., Chicago, Ill.; CDL:210050-B)

SUBST. CLASS = S.

DIRECT RVW TIME = (MH) START-DATE END DATE

REVIEWED BY: L.W. Touart
TITLE: Fisheries Biologist
ORG: EEB/HED
LOC/TEL:

SIGNATURE: L.W. Touart DATE: 1/5/83

APPROVED BY:
TITLE:
ORG:
LOC/TEL:

SIGNATURE: DATE:

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(TDR03B) DATA EVALUATION RECORD PAGE 1 OF

CASE GS0065 DICAMBA PM 500 06/09/82

CHEM 029806 Sodium dicamba (3,6-dichloro-2-anisic

BRANCH EEB DISC 40 TOPIC 05100542

FORMULATION 90 = FORMULATION NOT IDENTIFIED

FICHE/MASTER ID 00030102 CONTENT CAT 01

Fink, R. (1975) Final Report: Eight-Day Dietary LC-50--Mallard Ducks: Project No. 107-106. (Unpublished study including official analytical report, received Nov 18, 1976 under 876-255; prepared by Truslow Farms, Inc., submitted by Velsicol Chemical Corp., Chicago, Ill.; CDL:226933-D)

SUBST. CLASS = S.

DIRECT RVW TIME = (MH) START-DATE END DATE

REVIEWED BY: L.W. Tourtet
TITLE: Fisheries Biologist
ORG: EEB/HED
LOC/TEL:

SIGNATURE: L W Tourtet DATE: 1/10/83

APPROVED BY:
TITLE:
ORG:
LOC/TEL:

SIGNATURE: DATE:

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VALIDATION SHEET CRF #_____ PAGE ____ OF ____

FORMULATION:		
% a.i.	SC #	CHEMICAL NAME
26.5%		Banvel 2S

029806

IA	IB	T	FW	EC	R		

Validator: Charles A. Bowen II (151) Date: 8/11/78

Test Type: Eight Day dietary on Bobwhite quail

Test ID.# 233292

CITATION: Fink, Robert. 1977. Eight-Day Dietary LC50--Bobwhite Quail Banvel 2S Final Report. Conducted by Wildlife International LTD. Sponsored by Velsicol Chemical Corporation.

VALIDATION CATEGORY: Core for formulated product.

RESULTS: The acute LC50 of Banvel 2S in the Bobwhite quail is estimated by the testing facility to be greater than 10,000 ppm. The above value was, however, computed on the bases that Banvel 2S was assumed to contain 100% active ingredient. Banvel 2S contains only 26.5% active ingredient. The above toxicity value when adjusted for the technical amounts a LC50 value greater than 2650.0 ppm.

This value also represents a no effect level for Banvel 2S on 14 day old Bobwhite quail as no mortalities occurred. See attached abstract for details of test procedures.

VALIDATION CATEGORY RATIONALE:

The above study was found to (and) concur with the EPA's present guidelines concerning eight day dietary studies. No statistical analysis was conducted as no mortalities occurred.

CATEGORY REPAIRABILITY: N.A.